

**REMARKS**

This Response, filed in reply to the Office Action dated July 20, 2007, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1-13 and 16-23 are rejected. Claims 1, 3, 5, 6-8, 16 and 17 are currently amended and Claim 2 is canceled. Entry of these amendments is respectfully requested. Support for the amendments can be found throughout the specification, and at least in paragraphs [0035]-[0043] of the published specification.

***Information Disclosure Statement***

Applicants thank the Examiner for returning signed and initialed copies of the PTO Forms SB/08 submitted with the Information Disclosure Statements filed June 2, 2005, and September 1, 2006.

***Claims 3-13 and 17-23 are Not Anticipated by Brantman***

On page 2 of the Office Action, Claims 2-13 and 17-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Brantman (U.S. Patent No. 4,687,782). The Office asserts that Brantman discloses diet supplements comprising a combination of amino acids (i.e. leucine, isoleucine, valine, glutamine) “to promote muscle adaptation to strenuous exercise.” Further, the Office alleges that Brantman discloses numerical ranges for the amino acids used in the instant composition: leucine (20-45 parts), isoleucine (15-40 parts), valine (15-40 parts), glutamine (10-30 parts) (claims 5-6, 11-12, 20-23), wherein the relative proportions of the amino acids are preferably within 20% of the recited ranges.

The Office contends that although the composition of Brantman includes carnitine, the addition of carnitine does not materially affect the basic and novel characteristics of the claimed

invention because both compositions consist essentially of branched amino acids and a whey protein and are administered to improve muscle fatigue and promote muscle adaptation.

Applicants traverse the rejection, and respectfully submit that Brantman does not anticipate Applicants' invention as claimed. Applicants note that Claim 2 has is canceled.

First, Applicants respectfully submit that the originally-filed specification of the instant application discloses that Applicants' intended invention is a composition for the treatment of muscles that are already fatigued. Specifically, one of ordinary skill in the art reading Test Example 1 in paragraphs [0035]-[0043] of the published specification would clearly understand that the claimed composition is intended as a treatment for muscle fatigue because only upon completion of the treadmill exercise were the rats administered the claimed composition to determine its effect. At no point prior to or during exercise were the rats administered the claimed composition. Accordingly, Applicants respectfully submit that the instant composition is used as a treatment for pre-existing muscle fatigue. Thus, to even further define Applicants' claimed invention, Claims 1, 8, 16 and 17 have been amended to recite that the claimed composition is used as a "treatment." Applicants respectfully submit that in view of at least Test Example 1 in the specification as filed, one of skill in the art would understand that Applicants' claimed invention is directed towards a composition useful for the treatment of muscle fatigue, and that such is inherently disclosed within the specification, and at least within Test Example 1. Accordingly, Applicants submit that no new matter is added by way of these amendments.

Applicants respectfully submit that the composition disclosed by Brantman is distinct, and does not anticipate the claimed invention, at least in view of the following remarks. In column 3, lines 18-21, Brantman discloses that "the object of the present invention is to provide diet supplements which comprise BAA ... in order to promote muscle adaptation [to strenuous

exercise]” (emphasis added). In view of Brantman’s disclosure that an intended mechanism for promoting muscle adaptation is “to spare muscle protein and especially muscle BAA by providing the very substrate which is being utilized at the expense of muscle mass as well as liver protein” (column 3, lines 23-26) (emphasis added) and that “increased oxidation of protein and BAA during exercise is obligatory” (column 2, lines 58-60) (emphasis added), Applicants respectfully submit that one of ordinary skill in the art would understand that the method of Brantman is directed to the prevention of muscle fatigue, and not it’s treatment. Indeed, Brantman does not even contemplate that the administration of carnitine, isoleucine, leucine, valine and glutamine can be used to treat already fatigued muscles, but rather, suggest that they may be useful for preventing muscles from becoming fatigued. Thus, the instant application is directed to a composition for the treatment of fatigued muscles, whereas Brantman only discloses a method of prophylaxis. Thus, Brantman does not anticipate the instant claims because Brantman fail to even contemplate the use of a composition for the treatment of muscle fatigue. Brantman only disclose a prophylactic composition to prevent muscle fatigue. Accordingly, Brantman fail to teach each and every element of the claims, as is required to maintain a rejection under section 102.

Further, Claim 8 has been amended to further distinguish the claimed invention from that of Brantman. Specifically, Claim 8 has been amended to recite that leucine, isoleucine, valine, glutamine and whey protein are active ingredients of the claimed composition. Applicants respectfully submit that one of ordinary skill in the art would understand that the composition of Claim 8 contains leucine, isoleucine, valine, glutamine and a whey protein component as active ingredients, but that other ingredients, which do not materially affect the basic and novel characteristics of this mixture, would obviously be required but would be restricted to elements

necessary to produce a food or drink product that contains leucine, isoleucine, valine, glutamine and a whey protein component. Examples of such are provided in the paragraph bridging pages 8 and 9 of the originally filed specification. In contrast, Brantman clearly discloses that carnitine is an essential ingredient, as is disclosed in at least column 3, line 55 through column 4, line 12. Thus, Claim 8 and claims dependent therefrom are further distinguished from the composition disclosed by Brantman in that carnitine is not an essential element of the claimed composition.

**Withdrawal of the rejection is therefore respectfully requested.**

***Claim Rejections Under 35 U.S.C. § 103(a)***

On page 4 of the Office Action, Claims 1 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brantman. The Office asserts that Brantman discloses a composition comprising an amino acid mixture consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein, but that Brantman does not teach such a composition without carnitine. However, the Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Brantman and formulate a composition consisting of isoleucine, leucine, valine, glutamine, and a whey protein. The Office alleges that one of ordinary skill in the art would be motivated to administer the composition to an athlete and expect it to be successful in improving fatigue during exercise because Brantman teaches a composition consisting essentially of the branched amino acids, i.e. isoleucine, leucine, leucine, valine, glutamine, and a whey protein, which can be administered to promote muscle adaptation to strenuous exercise in a person.

Further, the Office alleges that Brantman discloses a composition that improves muscle during exercise, wherein the composition consists essentially of 0.025g carnitine, 0.5g glutamine,

0.625g isoleucine, 0.85g leucine, 0.625g valine, and 2.5g whey protein (col. 8 lines 5-18). As the amount of carnitine present (0.025 g) is the least compared with the other components in the composition described by Brantman, the Office contends that its absence would not interfere with the basic and novel characteristics of the claimed invention (i.e. which is to promote muscle adaptation to strenuous exercise). The Office asserts that carnitine is included in the composition to minimize the effect of ammonia that is generated during catabolism of amino acids, which can occur during strenuous exercise.

The Office concludes that one of ordinary skill in the art would recognize that a composition consisting of glutamine, isoleucine, leucine, valine, and whey protein alone is sufficient to provide therapeutic benefit in that it can provide the branched amino acids necessary for stimulating protein synthesis in skeletal muscle and in liver in order to improve muscle fatigue.

Applicants traverse the rejection, and respectfully submit that Brantman does not teach each and every element of the claimed invention, as is required to maintain a rejection under 35 U.S.C. § 103(a). Specifically, as mentioned above, the composition used by Brantman is distinct from the instantly claimed composition in that it is used for the purpose of promoting muscle adaptation to prevent muscle fatigue, whereas the instant composition is used as a treatment for fatigued muscles. Accordingly, Brantman does not render Claims 1 and 16 obvious for at least this reason.

Further, although the Office contends that the omission of carnitine from the composition disclosed by Brantman would be an obvious modification, Applicants respectfully disagree since as mentioned above, the different compositions have distinct applications. In this regard, column 3, lines 61-63 of Brantman discloses that “[c]arnitine is known to be required for the oxidation of

fat for calories, and that fat is a major fuel for skeletal muscle during exercise” (emphasis added). Thus, one of ordinary skill in the art would understand from this disclosure that Brantman includes carnitine to optimize fatty acid oxidation in muscles during exercise, in order to prevent the oxidation of muscle BAA. This is confirmed in column 4, lines 8-11, where Brantman states that the “present invention employs carnitine to optimize skeletal muscle function in relation to oxidation of fatty acids for calories.” Such disclosures further establish that Brantman discloses a method of prophylaxis, in contrast to the treatment method claimed in the instant application.

In sum, Claims 1 and 16 are not rendered obvious by Brantman for at least the following reasons. First, Brantman fails to disclose that the composition may be used as a treatment for fatigued muscles, and thus Brantman does not teach each and every element of the claims, as is required to maintain a rejection under section 103(a). Second, the inclusion of carnitine in Brantman’s composition is clearly an essential element for performing the method of Brantman, as is disclosed in at least column 3, line 55 through column 4, line 12 of Brantman, as it allows for increased fatty acid oxidation within muscles to lessen the need for anaerobic respiration and BAA oxidation, hence preventing muscle fatigue. Thus, Applicants respectfully submit that the composition of Brantman differs with regard to both composition and function, and therefore does not render obvious Claims 1 and 16.

**Withdrawal of the rejection is therefore respectfully requested.**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.116  
Application No.: 10/537,401

Attorney Docket No.: Q88294

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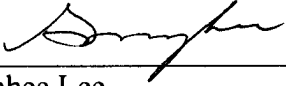
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